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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,331	11/09/2001	James C. Paulson	019957-011211US	3312

20350 7590 12/29/2004

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EXAMINER

PROUTY, REBECCA E

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/007,331

Applicant(s)

PAULSON ET AL.

Examiner

Rebecca E. Prouty

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1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.


NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 57,59, 61-65,67-70, 101, and 112.Claim(s) withdrawn from consideration: none.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


Rebecca E. Prouty
Primary Examiner
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The second declaration of Dr. Zopf submitted with the after-final response will not be considered because good and sufficient reasons why it was not earlier presented have not been shown. This declaration and applicants accompanying arguments contain substantial amounts of additional evidence regarding commercial success as evidence of non-obviousness. As the MPEP makes clear in section 716.03, an applicant who is asserting commercial success to support its contention of nonobviousness **bears the burden of proof** of establishing a nexus between the claimed invention and evidence of commercial success. The Federal Circuit has acknowledged that applicant bears the burden of establishing nexus, stating: "In the ex parte process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion that the sale constitute commercial success. Ex parte Remark, 15 USPQ2d 1498, 1503 (Bd. Pat. App. & Int. 1990). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success". As such applicants should have been aware that all evidence to support their position should have been presented prior to the final Office Action. Consideration of this declaration after-final would require substantial additional consideration.

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Applicants argue that the 103 rejection should be withdrawn as the primary references fail to disclose *in vitro*, commercial-scale sialylation methods that achieve at least 80% sialylation of the target sites as now claimed. Applicants argue the examiner has not pointed to any specific teaching of large scale production of modified glycoproteins in the cited art.

Applicants state that in the previous Office Action the examiner stated that the suggestion to scale up the disclosed methods is implicit in the art. Applicants argue however, that the examiner has not yet addressed, what in the art would lead one of skill to expect high levels of sialylation as previously claimed in claim 60 and currently claimed in claim 57. This is not persuasive because this was specifically addressed in the First Office Action. As stated therein Weinstein et al. teach the enzymatic properties of the sialyltransferases (i.e., rat liver ST6Gal I and ST3Gal III used in the methods taught by Bergh et al. and Maras et al. Weinstein et al. further teach conditions under which each of these enzymes can fully sialylate all available substrate (see Table 4). Furthermore, one of skill in the art would have reasonably expected to be able to achieve virtually complete sialylation of all available substrate galactose residues in view of the teaching of Weinstein et al. As such the examiner explicitly stated that

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the disclosures of Weinstein et al. is what would lead one of skill to expect high levels of sialylation as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Rebecca Prouty
Primary Examiner
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